Healthcare Services (Cord Blood Banking Service) Regulations 2021

Table of Contents

No. S 1037

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES
(CORD BLOOD BANKING SERVICE)
REGULATIONS 2021

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Healthcare Services (Cord Blood Banking Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

"acute hospital" includes any premises operated by a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use those premises as a private hospital, where the licence specifies that the private hospital is a medical hospital, a surgical hospital or both;

"Clinical Governance Officer" means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;

"cord blood" means the whole blood (including haematopoietic progenitor cells) remaining in placental and umbilical cord blood vessels after an umbilical cord has been clamped;

"incidental finding", in relation to any examination or test of an infant donor or the mother of an infant donor, means any observation, result or other finding about the infant donor or mother (as the case may be) that is disclosed or discovered by or during the examination or test and has potential health or reproductive importance to the infant donor or mother (as the case may be), but is not related to the purpose or objective of the examination or test;

"infant donor" means an infant from whose placenta or umbilical cord any cord blood is obtained;

"licensee" means a person who holds a licence to provide a cord blood banking service;

"medical history", in relation to an individual, includes —

(*a*) information about whether the individual has previously engaged in behaviour that exposes the individual to a high risk of contracting or developing any communicable disease; and

(*b*) information on whether the individual has a history of any genetic disease which may be inherited by a child of the individual;

"mother", in relation to an infant donor, means the woman who carries the infant

donor to delivery;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing a cord blood banking service;

"recipient" means an individual to whom cord blood is administered for the purposes of treatment;

"transplant", in relation to cord blood, means the administration of the cord blood to a recipient, whether the recipient is the infant donor of the cord blood, the mother of the infant donor or another individual;

"transplanting clinician", in relation to an acute hospital, means a medical practitioner who is authorised by the acute hospital to transplant cord blood to a recipient.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations, the provisions of these Regulations —

(*a*) apply in addition to the provisions of the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021); and

(*b*) prevail if, and to the extent that, there is any inconsistency between these Regulations and the Healthcare Services (General) Regulations 2021 insofar as the matter relates to an applicable licensee.

Skills and competencies of Clinical Governance Officer

4. For the purposes of section 24(3)(*b*) of the Act, an individual who has all of the following skills and competencies is suitably qualified to be appointed a Clinical Governance Officer for a cord blood banking service:

(*a*) registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(*b*) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of haematology;

(*c*) at least 5 years of work experience in —

(i) haematopoietic stem cell transplant;

(ii) transfusion medicine, provided that the working experience relates to the assessment, screening and evaluation of donors of cord blood;

(iii) blood banking;

(iv) cord blood banking; or

(v) any other activity relating to the provision of a cord blood banking service approved by the Director.

Quality management system

5.—(1) A licensee must establish and maintain an effective quality management system for the cord blood banking service provided by the applicable licensee relating to —

(*a*) the safety of infant donors, the mothers of infant donors and recipients;

(*b*) the safety, quality, potency and viability of cord blood collected, tested, processed, stored and distributed by the licensee; and

(*c*) the proper collection, testing, processing, storage and distribution of cord blood.

(2) The quality management system mentioned in paragraph (1) must provide for all of the following:

(*a*) the investigation of any occurrence or complaint that discloses or may disclose any weakness or inadequacy affecting the quality of the cord blood banking service;

(*b*) the identification and implementation of appropriate and effective actions to address any weakness or inadequacy mentioned in sub-paragraph (*a*) and prevent a recurrence;

(*c*) measures to ensure that the provision of the cord blood banking service complies with the Act, these Regulations and any other regulations made under the Act and any other applicable written law;

(*d*) the implementation of quality control measures for all cord blood collected, tested, processed, stored and distributed by the licensee, including measures pertaining to the safety, quality, potency and viability of the cord blood in relation to —

(i) the recruitment of infant donors and the mothers of infant donors;

(ii) the collection and transport of the cord blood;

(iii) the processing of the cord blood;